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Therapeutic Class Code: H3A,H3N

Therapeutic Class Description: Analgesics, Opioids; Analgesics, Opioid Agonist, NSAID

Combination

Medication (Short Acting)	
Abstral	
Actiq and generic fentanyl citrate lozenges	
Apadaz tablet and generic benzhydrocodone-acetaminophen tablet	
Ascomp	
butalbital-caffeine-acetaminophen with codeine	
butorphanol spray	
Capital with codeine suspension	
Codeine sulfate	
Demerol and generic meperidine	
dihydrocodeine-acetaminophen-caffeine	
Dilaudid and generic hydromorphone	
Dsuvia	
Fentora	
Fiorinal with codeine and generic butalbital compound with codeine	
hydrocodone/acetaminophen	
hydrocodone/ibuprofen	
Ibudone and generic hydrocodone/ibuprofen	
Lazanda	
Lorcet and generic hydrocodone/acetaminophen	
Lortab and generic hydrocodone/acetaminophen	
Levorphanol	
morphine	
Nalocet	
Norco and generic hydrocodone/acetaminophen	
Nucynta	

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1 8
Opana and generic oxymorphone
Oxaydo
oxycodone
oxycodone/acetaminophen
oxycodone/aspirin
oxycodone/ibuprofen
pentazocine-naloxone
Percocet and generic oxycodone/acetaminophen
PrimLev
Roxybond
Roxicodone and generic oxycodone
Subsys
Tylenol with codeine and generic acetaminophen with codeine
Ultracet and generic acetaminophen with tramadol
Ultram and generic tramadol
Vicodin and generic hydrocodone/acetaminophen
Xylon and generic hydrocodone/ibuprofen
Medication (Long Acting)
Arymo ER
Belbuca

Medication (Long Acting)	
Arymo ER	
Belbuca	
Butrans and generic buprenorphine patch	
Conzip and generic tramadol ER capsule	
Dolophine and generic methadone	
Duragesic and generic fentanyl	
Embeda	
Exalgo and generic hydromorphone ER	
Hysingla ER and generic hydrocodone ER	
Kadian and generic morphine sulfate ER	
MS Contin and generic morphine sulfate ER	

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MorphaBond ER	
morphine sulfate ER	
Nucynta ER	
Oxycontin and generic oxycodone ER	
oxymorphone ER	
tramadol ER	
Xtampza ER	
Zohydro ER Capsules and generic hydrocodone ER	

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21

Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination(includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

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Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing Guide:

https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Exemptions:

Prior authorization is not required for beneficiaries with a diagnosis of pain secondary to cancer.

Prior authorization is not required on <u>preferred short-acting opioids</u> up to the equivalent daily maximum dose of 90 MME/day for beneficiaries with Sickle Cell Disease.

Criteria:

Short-Acting preferred Opioid Analgesics

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 1) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.

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- Prior approval requests may be approved for up to 6 months
- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as to why the beneficiary needs continued opioid treatment and current plan of care
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (<a href="https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/position-statements/policy for the use of opiates for the treatment of pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain
 — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Short-Acting Non-preferred Opioid Analgesics

- Prior approval required for all non-preferred short acting-opioids
- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 1) or greater than the maximum daily dose per claim (Table 3).
- Prior approval required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.
- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as
 to why the beneficiary needs continued opioid treatment and current plan of care
- Prior approval requests may be approved for up to 6 months.
- The Beneficiary must have a documented failure within the past year of two-preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (<a href="https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy for the use of opiates for the treatment of pain), and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.

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- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long-Acting Preferred Opioid analgesics

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period.
- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 2) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for beneficiaries who have not tried a short acting opioid in the past 45 days before trying long acting regardless of dose or days supply. Prior approval requests should include reason that beneficiary has not or cannot use a short acting first.
- Prior approval is required for greater than 7 days supply.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits
- Prior approval requests may be approved for up to 3 months.
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (<a href="https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/position-statements/policy for the use of opiates for the treatment of pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.</p>
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long Acting Non-Preferred Opioid Analgesics

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period.
- Prior approval is required for all non-preferred long acting opioids

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- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day (Table 2) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for greater than 7 days supply.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits
- Prior approval requests may be approved for up to 3 months.
- The Beneficiary must have a documented failure within the past year of two-preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (<a href="https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/position-statements/Policy for the use of opiates for the treatment of pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Procedures

- Changes in strength will not require prior authorization.
- Prior authorization request forms will be accepted when submitted by facsimile telecommunication or web entry methods only.

Table 1

Short-acting- Daily dose limits for coverage	
Drug	Dose equivalent to 90 MME/day
benzhydrocodone	109.8mg/day
butorphanol	12.8mg/day
codeine products	600 mg/day
dihydrocodeine	900mg/day

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Short-action	ng- Daily dose limits for coverage
Drug	Dose equivalent to 90 MME/day
fentanyl citrate buccal, lozenges, sublingual (Abstral, Actiq, Fentora)	692 mcg/day
fentanyl citrate nasal spray (Lazanda)	562 mcg/day
fentanyl sublingual spray (Subsys)	500 mcg/day
hydrocodone/ acetaminophen	90 mg/day hydrocodone
hydrocodone	90 mg/day
hydromorphone (Dilaudid [®])	24mg/day
morphine immediate-release	90mg/day
oxycodone immediate-release	60mg/day
oxycodone/ acetaminophen	60mg/day
oxycodone/aspirin	60mg/day oxycodone
oxycodone/ ibuprofen	60mg/day oxycodone
oxymorphone immediate- release (Opana [®])	30mg/day

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Short-acting- Daily dose limits for coverage	
Drug	Dose equivalent to 90 MME/day
pentazocine	272 mg/day
tramadol (Ultram [®] and Ultracet [®])	400mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 2

Long-acting daily dose limits for coverage	
Drug	Dose equivalent to 90 MME/day
Dolophine [®] , Methadose [®] (methadone)	22.5mg/day
Duragesic [®] (fentanyl transdermal)	37.5μg/hr (one patch every 72 hours)
Embeda [®] (morphine/naltrexone)	90/3.6 mg/day
Exalgo [®] (hydromorphone)	24 mg/day
Hysingla ER [®] (hydrocodone extended-release tablet)	90 mg/day
Kadian [®] (morphine extended-release)	90 mg/day

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Long-acting daily dose limits for coverage	
Drug	Dose equivalent to 90 MME/day
levorphanol	8.1 mg/day
morphine extended- release capsule	90 mg/day
MS Contin [®] , Oramorph SR [®] (morphine controlled-release)	90mg/day
OxyContin [®] (oxycodone controlled-release)	60 mg/day
oxymorphone extended- release	30mg/day
tramadol ER (Conzip [®] and Ultram ER [®])	300mg/day
Zohydro ER [®] (hydrocodone extended- release capsule)	90 mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 3

Maximum daily dose per claim	
Drug	Max Dose/Day
acetaminophen products	4 grams/day Acetaminophen
ibuprofen products	3.2 grams/day ibuprofen

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Maximum daily dose per claim	
Drug	Max Dose/Day
Aspirin products	4 grams/day aspirin
tramadol (Ultram [®] and Ultracet [®])	400mg/day
tramadol ER (Conzip [®] and Ultram ER [®])	300mg/day

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References

- 1. Drugs Facts and Comparison 4.0 (2008). Opioid Analgesics. Wolters Kluwer Health, Inc. www.online.factsandcomparisons.com.
- 2. Equi analgesic Dosing of Opioids for Pain Management. Pharmacist's Letter/Prescriber's Letter. September 2004: Volume 20, Number 200915.
- 3. Veterans Health Administration, Department of Defense. VA/DoD Clinical practice guideline for the management of opioid therapy for chronic pain. Washington, DC: Veterans Health Administration, Department of Defense; March 2003.
- 4. Labby, D, Kodor, M, Aman, T. Opioids and Chronic Non-Malignant Pain: A Clinician's Handbook. Care Oregon; 2003:95.
- 5. Clinical Pharmacology. Gold Standard. Elsevier Co. 2008.www.clinicalpharmacology.com
- 6. Massachusetts General Hospital Cares About Pain Relief. Adapted from Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain. Fourth Edition. Chicago: American Pain Society, 1999. www.massgeneral.org/painrelief/mghpain_equichart.htm.
- 7. Cephalon, Inc. Actiq package insert. Salt Lake City, UT, 2007.
- 8. Cephalon, Inc. Fentora package insert. Salt Lake City, UT 2007.
- 9. Oregon Health & Science University. Chronic Pain Management. Opioids and Chronic Non-Malignant Pain: A Clinicians' Handbook. http://www.ohsu.edu/ahec/pain/painmanual.html.
- 10. Purdue Pharma L.P. Butrans package insert. Stamford, CT 06901.
- 11. Purdue Pharma L.P. Hysingla ER package insert. 11/2014, Stamford, CT 06901.
- 12. Acura Pharmaceuticals, Inc. Oxecta package insert. Updated 01/2014, Palatine, Illinois 60067
- 13. Depomed, Inc. Lazanda package insert. March 2015. Newark, CA.
- 14. Endo Pharmaceuticals. Belbuca package insert. October 2015. Malvern, PA.
- 15. Mallinckrodt, LLC. Xartemis XR package insert. March 2014. Hazelwood, MO.
- 16. Patheon Pharmaceuticals. Xtampza ER package insert. April 2016. Cincinnati, Ohio.
- 17. https://www.cdc.gov/drugoverdose/pdf/calculating total daily dose-a.pdf
- 18. https://www.cms.gov/Medicare/Prescription-Drug-CovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-March-2015.pdf
- 19. Inspirion Delivery Sciences. Roxybond package insert. April 2017. Valley Cottage, NY.
- 20. Forte-Bio Pharmaceuticals, LLC. Nalocet package insert. July 2018. Las Vegas, NV 89146.
- 21. Apadaz [package insert]. Coralville, IA: KemPharm, Inc; February 2018.

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Criteria Change Log

03/04/2002	Criteria effective date- (original name
	Oxycontin)
08/04/2008	Name changed to Schedule II Narcotics
10/11/2012	Add Nucynta ER
03/13/2014	Add Zohydro
12/08/2014	Add Butrans NDC's
03/03/2015	Add new oxycodone GCN's
05/18/2015	Add Hysingla
06/10/2015	Add Embeda/Exalgo
06/16/2015	Add new morphine NDC's
01/21/2016	Add Lazanda, Oxecta
06/16/2016	Add Belbuca
08/27/2017	Dose limits changed to 120mme/day and
	limits added for 14 days supply
01/02/2018	limits added for 5 and 7 days supply
06/01/2018	Change daily limit to 90 mme and add CIII
	and CIV's
11/20/2018	Remove special criteria for Zohydro
02/13/2019	Add Roxybond
07/12/2019	Add Nalocet
09/17/2019	Add tramadol ER dose limits to chart. Were
	already programmed but only put in short
	acting chart originally. Add Apadaz and add
	benzhydrocodone MME's to chart
	Moved Conzip to Long Acting
07/09/2020	Updated EPSDT links
	Removed GCN's
	Added exemption for Sickle Cell for short
02/01/2021	acting opioids at 90mme's or less/day
03/01/2021	Removed obsolete products: Avinza, Endodan, Fioricet with codeine, Hycet,
	Magnacet, Onsolis, Oxecta, Percodan,
	Synalgos-DC & generic, Ultram ER,
	Vicoprofen, Xartemis XR, Xodol, Reprexain,
	and Zamicet
	Added: benzhydrocodone/APAP (generic
	Apadaz), Dsuvia, hydrocodone/ibuprofen
	(generic Ibudone), morphine sulfate ER
	(generic Avinza), buprenorphine patch
	(generic Butrans), tramadol ER capsule
	(generic Conzip), Morphabond ER
	Dose table clarification
02/01/2022	Add generic Hysingla ER